means extending radially outward of said end surface means and positioning surface means.

165. An apparatus as set forth in claim 160 further including actuator means disposed adjacent to said handle and connected with said pusher surface means for moving said pusher surface means relative to said positioning surface means to move the anchor along said positioning surface means in a direction away from said handle.

pusher surface means is movable relative to said positioning surface means and end surface means to move the anchor relative to said shaft to facilitate disengagement of the anchor from said shaft during insertion of the anchor into body tissue.

including actuator means disposed adjacent to said handle and connected with said pusher surface means, said actuator means being movable relative to said handle to move said pusher surface means relative to said positioning surface means.

REMARKS

Reconsideration of this application is respectfully requested.

Claim 7, which was indicated as being allowable, has been rewritten in independent form as claim 73. Claim 8, 9 and 74 through 80 depend from claim 73. Therefore, it is believed that these claims are in condition for allowance.

Claim 20, which was indicated as being allowable, has been rewritten in independent form as claim 81. Therefore, it is believed that this claim is in condition for allowance.

Claim 22, which has been indicated as being allowable, has been rewritten in independent form as claim 82. Claims 83 through 87 depend from claim 82. Therefore, it is believed that these claims are in condition for allowance.

Claim 23, which was indicated as being allowable, has been rewritten in independent form as claim 88. Claims 89 through 96 depend from claim 88. Therefore, it is believed that these claims are in condition for allowance.

Claim 28, which was indicated as being allowable, has been rewritten in independent form as claim 97. Claims 98 through 103 depend from claim 97. Therefore, it is believed that these claims are in condition for allowance.

Claim 32, which was indicated as being allowable, has been rewritten in independent form as claim 104. Claims 105 through 107 depend from claim 104. Therefore, it is believed that these claims are in condition for allowance.

Claim 34, which was indicated as being allowable, has been rewritten in independent form as claim 108. Claims 109 through 111 depend from claim 108. Therefore, it is believed that these claims are in condition for allowance.

Claim 36, which was indicated as being allowable, has been rewritten in independent form as claim 112. Claims 113 through 117 depend from claim 112. Therefore, it is believed that these claims are in condition for allowance.

Claim 37, which was indicated as being allowable, has been rewritten in independent form as claim 118. Therefore, it is believed that this claim is in condition for allowance.

Claim 38, which was indicated as being allowable, has been rewritten in independent form as claim 119. Therefore, it is believed that this claim is in condition for allowance.

Claim 45, which was indicated as being allowable, has been rewritten in independent form as claim 120. Claims 121 through 127 depend from claim 120. Therefore, it is believed that these claims are in condition for allowance.

Claim 48, which was indicated as being allowable, has been rewritten in independent form as claim 129. Therefore, it is believed that this claim is in condition for allowance.

Claim 49, which was indicated as being allowable, has been rewritten in independent form as claim 130. Therefore, it is believed that this claim is in condition for allowance.

Claim 50, which was indicated as being allowable, has been rewritten in independent form as claim 131. Claims 132 through 139 depend from claim 131. Therefore, it is believed that these claims are in condition for allowance.

Claim 51, which was indicated as being allowable, has been rewritten in independent form as claim 140. Claims 141 through 144 depend from claim 140. Therefore, it is believed that these claims are in condition for allowance.

Claim 52, which was indicated as being allowable, has been rewritten in independent form as claim 145. Claim 53 and claims 146 through 149 depend from claim 145. Therefore, it is believed that these claims are in condition for allowance.

Claim 64, which was indicated as being allowable, has been rewritten in independent form as claim 150. Claims 62 and 63 depend from claim 150. Therefore, it is believed that these claims are in condition for allowance.

Independent claim 24 is directed to a method of positioning a suture anchor in body tissue. The method includes providing an anchor which has a passage which extends between first and second surface areas on the anchor and an inserter having an end portion and a pusher surface. The anchor and inserter are moved together into body tissue with the end portion of the inserter extending into the passage in the anchor. While performing the step of moving the anchor and inserter together into body tissue, the pusher surface on the inserter engages the second surface area on the anchor. The step of moving the anchor and inserter together into body tissue includes transmitting force from the pusher surface area on the inserter to the second surface area on the anchor.

Claim 24 was rejected as being unpatentable over a combination of the patents to DiPoto et al. (5,258,016) and the patent to Hayhurst et al. (5,041,129). However, these patents do not disclose moving an anchor and inserter together into body tissue with a pusher surface on the inserter engaging a surface area on the anchor. Furthermore, these patents do not disclose moving the anchor and inserter together into the body tissue while transmitting force from the pusher surface on the inserter to the second surface area on the anchor.

In the patent to DiPoto et al., a guide wire 352 is inserted through a passageway 350 in the anchor 310 (Fig. 27).

The guide wire is then positioned in the hole 318 in the manner illustrated in Fig. 27. The anchor is then slid along the guide wire (col. 10, lines 48-52). The patent to DiPoto et al. does not contemplate that the anchor and inserter will be moved together into body tissue in the manner set forth in claim 24. In addition, the patent to DiPoto et al. does not contemplate that force will be transmitted from a pusher surface on the inserter to a surface on the anchor during movement of the anchor and the inserter together into body tissue.

Claims 25-27 and 29-31 depend from claim 24 and define over the prior art for substantially the same reasons as claim 24 and by virtue of the method steps set forth in these claims taken in combination with the method steps of claim 24. Specifically, claim 25 sets forth the step of separating the inserter and the anchor after performing the step of moving the anchor and inserter together into body tissue.

Claim 26 depends from claim 25 and sets forth the step of separating the anchor and the inserter as including moving the pusher surface toward the end portion of the inserter.

Claim 27 depends from claim 25 and sets forth the step of separating the inserter and anchor as including applying force against the second surface area on the anchor and moving the anchor relative to the end portion of the inserter under the influence of force applied against the second surface area on the anchor.

Claim 29 depends from claim 24 and sets forth the step of moving the anchor and inserter together into body tissue as including initiating the formation of an opening in a surface

area on body tissue with an end portion of the inserter at a location ahead of the first surface area on the anchor. As was recognized by the Examiner, the patent to DiPoto et al. does not disclose the step of initiating formation of an opening in a surface area on body tissue with an inserter. The patent to Hayhurst et al. discloses the step of initiating an opening on body surface with the sharpened tip of the leading edge 33 of the insertion tool 28. However, the insertion tool 28 of Hayhurst et al. does not apply force against the anchor 10. In the patent to Hayhurst et al., a separate pusher tube 32 is provided to apply force against the trailing end of the anchor.

Claim 30 depends from claim 24 and sets forth the step of moving the anchor and inserter together into body tissue as including penetrating the body tissue at a location ahead of the first surface area on the anchor.

Claim 31 depends from claim 24 and sets forth the step of inserting a suture through an opening in the anchor. The step of moving the anchor and inserter together into body tissue is performed with the suture extending through the opening in the anchor.

Independent claim 33 is directed to an apparatus which includes a suture disposed in engagement with an anchor. A shaft extends from a manually engageable handle through a passage in the anchor. The shaft has a pointed end which extends away from the first surface area on the anchor in a direction away from the handle. The shaft has a pusher surface which is spaced from the pointed end of the shaft by a distance which is the same as the distance between first and second

surface areas on the anchor. The pointed end of the shaft is effective to penetrate body tissue in <u>advance</u> of the anchor. The pusher surface is effective to apply force against the <u>second</u> surface area on the anchor upon insertion of the anchor into body tissue.

Claim 33 was rejected as being unpatentable over a combination of the patents to DiPoto et al. (5,258,016) and Hayhurst et al (5,041,129). However, claim 33 sets forth a manually engageable handle and a shaft which extends from the handle. The shaft has a pointed end. In addition, the shaft has a pusher surface which is spaced from the pointed end of the shaft by a distance which is the same as the distance between first and second surface areas on the anchor. The pointed end of the shaft is effective to penetrate body tissue in advance of the anchor. The pusher surface is effective to apply a force against the second surface area on the anchor upon insertion of the anchor into body tissue.

The prior art does <u>not</u> disclose an apparatus which includes a manually engageable handle and a shaft wherein:

- (1) the shaft has a pointed end and a pusher surface which is spaced from the pointed end by a distance which is the <u>same</u> as the distance between first and second end surfaces on the anchor,
- (2) the pusher surface being effective to apply force against the second surface area on the anchor upon insertion of the anchor into body tissue.

The guide wire 352 of DiPoto et al. does \underline{not} have a pusher surface. More specifically, the guide wire 352 of DiPoto et

al. does <u>not</u> have a pusher surface which is spaced from the pointed end of a shaft by a distance which is the <u>same</u> as the distance between surface areas on the anchor.

Claim 35 depends from claim 33 and defines over the prior art for substantially the same reasons as does claim 33 and by virtue of the structure and function set forth in claim 35 taken in combination with the structure and function of claim 33. Specifically, claim 35 sets forth the pusher surface as being movable relative to the pointed end of the shaft to move the anchor relative to the pointed end of the shaft.

Rejected claim 47 has been rewritten in independent form as claim 128. Claim 128 is directed to an apparatus for use in anchoring a suture in body tissue with an anchor having a passage which extends between first and second surface areas on the anchor. The apparatus includes a handle and a shaft which is connected with the handle. The shaft extends outward from the handle and extends through the passage in the anchor during insertion of the anchor into body tissue.

The shaft is set forth in claim 128 as having end surface means for piercing body tissue ahead of the first end surface area on the anchor during insertion of the anchor into body tissue. The shaft has pusher surface means for transmitting force to the second surface area on the anchor to push the anchor during insertion of the anchor into body tissue. The shaft is integrally formed as one piece. The pusher surface means is disposed on the shaft in a fixed relationship with the end surface means.

Claim 47, which has been rewritten in independent form as claim 128, was rejected as being unpatentable over a combination of the patents to DiPoto et al. (5,258,016) in view of the patent to Hayhurst et al. (5,041,129). However, claim 128 defines over these patents by setting forth a shaft which is connected with a handle and has a pusher surface for transmitting force to the anchor to push the anchor during insertion of the anchor into body tissue. The shaft is integrally formed as one piece and the pusher surface is disposed on the shaft in a <u>fixed</u> relationship with the end surface which pierces the body tissue.

In the patent to DiPoto et al., the <u>shaft</u> does not have a pusher surface which is disposed in a <u>fixed</u> relationship with the end surface of the shaft. In the patent to Hayhurst et al., the insertion tool 28 does <u>not</u> have a pusher surface which is disposed in a fixed relationship with the sharpened tip of the leading edge 33. Thus, the patent to Hayhurst et al. provides a <u>separate</u> pusher tube 32. The prior art does <u>not</u> disclose:

- (1) a shaft which extends outward from a handle through a passage in an anchor and has an end surface for piercing body tissue,
- (2) wherein the shaft is integrally formed as one piece and has a pusher surface disposed on the shaft in a fixed relationship with the end surface which pierces body tissue.

Independent claim 151 is directed to a method of positioning a suture anchor in body tissue. The method

includes engaging a surface area on the body tissue with a leading end portion of a suture anchor inserter which extends through a suture anchor engaged by a suture. The surface area on the body tissue is pierced with the leading end portion of the suture anchor inserter while the suture anchor inserter extends through the suture anchor.

In addition, claim 151 sets forth the step of moving the leading end portion of the suture anchor inserter and the suture anchor together into an opening formed in the body tissue during performance of the step of piercing body tissue with the leading end portion of the suture anchor inserter. The step of moving the leading end portion of the suture anchor inserter and suture anchor together into an opening formed in body tissue includes applying force against a trailing end portion of the suture anchor with the suture anchor inserter to prevent relative movement between the suture anchor inserter and the suture anchor.

Claim 151 defines over the prior art by setting forth the step of moving the leading end portion of the suture anchor inserter and the suture anchor together into an opening formed in body tissue. In the patent to DiPoto et al., the tip 354 of the guide wire 352 is moved into the hole 318 (Fig. 27) before the anchor 310 is moved into the hole. There is nothing in the patent to DiPoto et al. which even remotely suggests that the guide wire and anchor will be moved together into an opening formed in body tissue during piercing of the body tissue. In addition, claim 151 defines over the prior art by setting forth the step of applying force against a trailing end portion of

the suture anchor with the suture anchor inserter to prevent relative movement between the suture anchor and the suture anchor inserter during movement of the leading end portion of the suture anchor inserter and the suture anchor into an opening formed in body tissue.

Claims 152 through 159 depend from claim 151 and define over the prior art for substantially the same reasons as does claim 151 and by virtue of the structure and function set forth in these claims taken in combination with the structure and function of claim 151. Specifically, claim 151 sets forth the step of inserting a suture through an opening in the suture anchor and inserting the leading end portion of the suture anchor inserter into the opening in the suture with the suture in the opening in the suture anchor. The step of inserting the leading end portion of the suture anchor inserter into the opening in the suture anchor includes sliding the leading end portion of the suture anchor inserter along a portion of the suture which extends generally parallel to a direction in which the leading end portion of the suture anchor inserter is moved into the suture anchor. There is nothing in the prior art which even remotely suggests sliding a suture anchor inserter along a portion of a suture which extends generally parallel to a direction in which the leading end portion of the suture anchor inserter is moved into a suture anchor.

Claim 153 depends from claim 151 and sets forth the step of engaging a surface area on body tissue with the leading end portion of the suture anchor inserter as including engaging the surface area with a <u>pointed</u> end of the suture anchor inserter.

The step of piercing the surface area on the body tissue includes initiating formation of an opening in the surface area on the body tissue with the pointed end of the suture anchor inserter.

Claim 154 depends from claim 151 and sets forth the step of withdrawing the leading end portion of the suture anchor inserter from the suture anchor after moving the leading end portion of the suture anchor inserter and the suture anchor together into the opening formed in the body tissue. The step of withdrawing the leading end portion of the suture anchor inserter from the suture anchor includes applying force against the trailing end portion of the suture anchor to push the suture anchor toward the leading end portion of the suture anchor inserter.

Claim 155 depends from claim 151 and sets forth the step of changing the orientation of the suture anchor relative to the leading end portion of the suture anchor inserter after moving the suture anchor into body tissue.

Claim 156 depends from claim 155 and sets forth the step of changing the orientation of the suture anchor relative to the leading end portion of the suture anchor inserter as including tensioning the suture.

Claim 157 depends from claim 156 and sets forth the step of changing the orientation of the suture anchor as including applying force against a trailing end surface of the suture anchor.

Claim 158 depends from claim 151. Claim 158 sets forth the step of disengaging the suture anchor from the leading end

portion of the suture anchor inserter with the suture anchor in the body tissue. The step of disengaging the suture anchor from the leading end portion of the suture anchor inserter includes applying force against the trailing end portion of the suture anchor with the suture anchor inserter.

Claim 159 depends from claim 158 and sets forth the step of applying force against the trailing end of the suture anchor as including moving a force transmitting surface disposed on the suture anchor inserter in a direction toward a leading end of the suture anchor inserter.

Independent claim 160 is directed to an apparatus for use in anchoring a suture in body tissue with an anchor having a passage which extends between first and second end surfaces on the anchor. The apparatus includes a handle and a shaft which is connected with the handle. The shaft extends outward from the handlé and extends through a passage in the anchor during insertion of the anchor into body tissue. The shaft has an end surface for piercing body tissue ahead of the first surface area on the anchor during insertion of the anchor into body tissue. The shaft has a positioning surface for engaging an inner surface of the passage in the anchor to position the anchor relative to the shaft. The positioning surface extends through the passage in the anchor during insertion the anchor into body tissue to position the anchor relative to the shaft. The shaft has a pusher surface for transmitting force to the second surface area on the anchor to push the anchor during insertion of the anchor into body tissue. The pusher surface projects outward of the positioning surface to enable the

pusher surface to engage the second surface area on the anchor during insertion of the anchor into body tissue.

Claim 160 defines over the prior art by setting forth the suture anchor inserter having a shaft which extends through the passage in an anchor during insertion of the anchor into body tissue and wherein the shaft includes:

- (1) an end surface for <u>piercing</u> body tissue ahead of the anchor during insertion of the anchor into body tissue.
- (2) a positioning surface for engaging an inner surface of a passage in the anchor,
- (3) a pusher surface which projects outward of the positioning surface and transmits force to the anchor to push the anchor during insertion of the anchor into body tissue.

The guide wire 352 of DiPoto et al. does <u>not</u> have a pusher surface which transmits force to the end surface on an anchor to push the anchor during insertion of the anchor into body tissue. In addition, the guide wire of DiPoto does not pierce body tissue ahead of the anchor during insertion of the anchor into body tissue.

Claims 161 through 167 depend from claim 160 and define over the prior art for substantially the same reasons as does claim 160 and by virtue of the structure and function set forth in these claims taken in combination with the structure and function of claim 160. Specifically, claim 161 sets forth the shaft as including an inner member which is connected with the handle and an outer member which encloses the inner member.

The pusher surface is disposed on the outer member and is movable relative to the inner member along the positioning surface means.

Claim 162 depends from claim 160 and sets forth the shaft as being integrally formed as <u>one</u> piece. The pusher surface is disposed on the shaft in a <u>fixed</u> relationship with the positioning surface and the end surface.

Claim 163 depends from claim 160 and sets forth a <u>spring</u> which is resiliently <u>deflectable</u> to move relative to the shaft between an engaged position in which the spring engages the inner surface of the passage in the anchor to retain the anchor against movement relative to the shaft and a disengaged position in which the spring is ineffective to retain the anchor against movement relative to the shaft.

Claim 164 depends from claim 160 and sets forth the end surface as being pointed and as having a generally conical configuration. The positioning surface has a generally cylindrical configuration. The pusher surface has a generally annular configuration. The end surface, positioning surface and pusher surface are disposed in a coaxial relationship with the pusher surface extending radially <u>outward</u> of the end surface and the positioning surface.

Claim 165 depends from claim 160 and sets forth an actuator as disposed adjacent to the handle and as connected with the pusher surface. The actuator is operable to move the pusher surface relative to the positioning surface to thereby move the anchor along the positioning surface in a direction away from the handle.

Claim 166 depends from claim 160 and sets forth the pusher surface as being movable relative to the positioning surface and the end surface to move the anchor relative to the shaft.

Claim 167 depends from claim 166 and sets forth an actuator disposed adjacent to the handle and connected with the pusher surface. The actuator is movable relative to the handle to move the pusher surface relative to the positioning surface.

In view of the foregoing remarks, it is believed that the claims in this application clearly and patentably define over the prior art. Therefore, it is respectfully requested that the claims be allowed and this application passed to issue. If for any reason the Examiner believes that a telephone conference would expedite the prosecution of this application, it is respectfully requested that he call applicant's attorneys in Cleveland, Ohio at 621-2234, area code 216. Please charge any deficiency in the fees for this application to our Deposit Account No. 20-0090.

Respectfully submitted,

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